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By: _____
Nancy Foster

PATENT
Customer No. 22,852
Attorney Docket No. 06843.0052-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Sanjay D. KHARE	Group Art Unit: 1646
Application No.: 10/748,112	Examiner: MERTZ, Prema Maria
Filed: December 29, 2003	
For: COMBINATION THERAPY WITH CO-STIMULATORY FACTORS	Confirmation No. 1751

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO OFFICE ACTION (RESTRICTION REQUIREMENT)

Applicant now responds to the Office Action (Restriction Requirement) mailed September 26, 2006 ("Restriction Requirement"). The period for reply has been extended two months by the Petition for Two Month Extension of Time and required fee filed herewith. The Examiner required restriction to one of 116 different groups.

Applicant elects Group 58, claims 104, 110, and 113 to 121, with traverse.

In the Restriction Requirement, the Examiner subdivided claims which are generic for "treating an inflammatory or an autoimmune condition" into six different groups, each group specific for a different inflammatory or autoimmune condition. For example, the Examiner has defined six different groups that consist of the claims 104,

110, and 113 to 121. Those groups are Groups 58, 63, 68, 73, 78, and 83. The only independent claim in each of those groups is claim 104, which recites:

> A method for treating an inflammatory or an autoimmune condition, which comprises administering a therapeutically effective amount of (i) at least one of an AGP3 inhibitor, a BAFFR inhibitor, and a TACI inhibitor, and (ii) an TNF-α inhibitor.

Thus, claim 104 is a generic method for treating an inflammatory or an autoimmune condition. The Examiner has subdivided that generic claim into six groups based on dependent claim 119, which recites:

> The method of claim 104, wherein the condition treated is selected from rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, graft rejection, psoriasis, and inflammatory bowel disease.

Thus, Groups 58, 63, 68, 73, 78, and 83 differ only in the inflammatory or autoimmune condition which is treated in the Group. For example, the Examiner defines Group 58 as:

> Group 58. Claims 104, 110, and 113-121 are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab, and D2E7, classified in Class 514, subclass 2.
>
> See Restriction Requirement at page 10. In comparison, the Examiner defines Group 63 as:
>
> Group 63. Claims 104, 110, and 113-121 are drawn to a method of treating psoriatic arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab, and D2E7, classified in Class 514, subclass 2.
>
> See id.

The Examiner similarly subdivided claims with respect to the TNF-α inhibitor in claim 104. Whereas, as shown above, claim 104 is generic for TNF-α inhibitors, the Examiner has required restriction to particular TNF-α inhibitors disclosed in various

dependent claims. Thus, for example, Group 58, shown above, is specific for etanercept, infleximab, and D2E7, which are TNF-α inhibitors found in dependent claim 110. In comparison, the Examiner defines Group 59 as:

> Group 59. Claims 104, 111, and 113-121 are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

See id.

At the outset, applicant provides the following comments. The Examiner's division of groups effectively subdivides generic claims. "Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions.... If restriction is improper under either practice, it should not be required." MPEP § 806.04(b) at 800-42. Furthermore, "[t]here are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application would be proper, but presented in the same case are one or more claims (generally called 'linking ' claims) inseparable therefrom and thus linking together the otherwise divisible inventions" MPEP § 809 at 800-52. "Linking claims must be examined with and thus are considered part of the invention elected." Id. In this case, the Examiner does not define claim 104 as a linking claim. Nor does the Examiner request a species election of one of the different conditions recited in dependent claim 119 and one of the different TNF-α inhibitors found in the claims that depend from claim 104. Instead, the Examiner divides the generic claim into subgroups.

The Examiner, however, cannot force the applicant to amend the claims by requiring restriction to particular species and refusing to examine a generic claim. For example, in the context of Markush-type claims, "[f]ollowing election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability." See MPEP § 803.02 at page 800-5. With regard to linking claims, the MPEP states:

> [w]hen all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claims directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.

See MPEP § 809 at page 800-62. Because the Examiner has no authority to force applicants to limit the scope of the claim through a restriction requirement, if the Examiner maintains the present restriction requirement, and the elected species are found allowable, applicant understands that the Examiner must continue to search and examine claim 104 to determine its patentability as written.

In any event, applicant asserts that the restriction requirement is improper because the Examiner failed to make the required *prima facie* showing of a serious burden to search and examine the entire application.

> Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the examiner if restriction is not required, i.e., the reasons for insisting upon restriction therebetween as set forth in the following sections.

See MPEP § 808 at page 800-50. To show a serious burden, the examiner must show by appropriate explanation one of the following: (A) separate classification of claims; (B) a separate status in the art when they are classifiable together; or (C) a different field of

search. See MPEP § 808(2) at page 800-51 to 52. "Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions." See id. at page 800-52.

In the Restriction Requirement, the Examiner alleged that "inventions 1-116 are independent and distinct, each from the other, because the methods are practiced with materially different products, which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes." See Restriction Requirement at page 19. The Examiner then provided several examples of what the Examiner apparently views as burdensome searches. For example, the Examiner compares search and consideration of a method of treating rheumatoid arthritis using sTNFRI with search and consideration of a method of treating rheumatoid arthritis using etanercept. See id. The Examiner also alleged that "[s]eparate search terms would be required for searching the literature, e.g., a literature search for an association of s-TNFR-II with rheumatoid arthritis would not necessarily reveal art for an association of the polypeptide of SEQ ID NO: 4 with rheumatoid arthritis." See id. pages 19 to 20.

The Examiner, however, does not address why searching all of the conditions recited in, e.g., claim 119 would create a serious burden. Thus, no *prima facie* showing of serious burden was made with respect to those conditions. No explanation was provided showing a separate classification, a separate status in the art, or a different field of search.

Similarly, the Examiner has not made a *prima facie* showing of serious burden with respect to different species of TNF-α inhibitors. The Examiner alleged that "[s]eparate search terms would be required for searching the literature, e.g., a literature search for an association of s-TNFR-II with rheumatoid arthritis would not necessarily reveal art for an association of the polypeptide of SEQ ID NO: 4 with rheumatoid arthritis" See id. pages 19 to 20. However, that allegation, even if true, falls short of demonstrating a different field of search. "Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries[)] a different field of search is shown...." See MPEP § 808.02 at 800-52. Thus, the standard is not whether a search would "necessarily reveal art" relevant to another search. The standard is whether "it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other inventions." The Examiner has made no such allegation of the likelihood of finding pertinent art. Furthermore, applicants assert that a search based on one particular TNF-α inhibitor would likely reveal art pertinent to other TNF-α inhibitors. Thus, no *prima facie* showing of serious burden was made based on a different field of search in the Restriction Requirement. Nor did the Examiner provide a showing of a separate classification or a separate status in the art. In fact, the Examiner has classified all of the groups in Class 514, subclass 2.

Thus, the Examiner failed to make a *prima facie* showing of serious burden, and therefore, applicant respectfully asserts that the restriction requirement with respect to at least Groups 55 to 84 (corresponding to claims 104 to 121) is improper. Accordingly,

applicant respectfully requests reconsideration and withdrawal of the restriction requirement, at least with respect to Groups 55 to 84. Applicant requests that the Examiner examine at least Groups 55 to 84 together in this application.

Species Election

If applicant elects any of groups 55 to 84, the Examiner required election of a species of AGP3, TACI, or BAFFR inhibitor selected from (a) TACI soluble receptor molecule, (b) peptide inhibitor of AGP3, (c) AGP3 peptibody, or (d) a protein of SEQ ID NO.: 1. See Restriction Requirement at page 21. Applicant elects species (b), a peptide inhibitor of AGP3. Claims 104, 110, 113, 116, 119 to 121 read on the elected species.

Please grant any extensions of time required to enter this Amendment and Response, and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: December 26, 2006

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